DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 522

Display Date 12.1.98
Publication Date 12.2
Certifier C.W.M.D.N

Implantation or Injectable Dosage Form New Animal Drugs; Butorphanol Tartrate

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of an abbreviated new animal drug application (ANADA) filed by Intervet, Inc. The ANADA provides for use of butorphanol tartrate injection for horses for the relief of pain associated with colic and postpartum pain in adult horses and yearlings.

EFFECTIVE DATE: (*Insert date of publication in the* **Federal Register**.)

FOR FURTHER INFORMATION CONTACT: Lonnie W. Luther, Center for Veterinary Medicine (HFV–102), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0209.

SUPPLEMENTARY INFORMATION: Intervet, Inc., 405 State St., P.O. Box 318, Millsboro, DE 19966–0318, filed ANADA 200–239 that provides for veterinary prescription use of Dolorex® (butorphanol tartrate) injection intravenously for horses for the relief of pain associated with colic and postpartum pain in adult horses and yearlings.

ANADA 200–239 is approved as a generic copy of Fort Dodge Animal Health's NADA 135–780 for Torbugesic® for horses. The ANADA is approved as of September 28, 1998, and the regulations are amended in 21 CFR 522.246(b) to reflect the approval. The basis for approval is discussed in the freedom of information summary.

In accordance with the freedom of information provisions of 21 CFR part 20 and 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support

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approval of the application may be seen in the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

The agency has determined under 21 CFR 25.33(a)(1) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

List of Subjects in 21 CFR Part 522

Animal drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 522 is amended as follows:

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 522 continues to read as follows:

Authority: 21 U.S.C. 360b.

2. Section 522.246 is amended by revising paragraph (b) to read as follows:

§ 522.246 Butorphanol tartrate injection.

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(b) *Sponsors.* Approval to firms identified in § 510.600(c) of this chapter for use as indicated:

(1) See No. 057926 for use as in paragraph (c)(2) of this section.

(2) See No. 000856 for use as in paragraphs (c)(1), (c)(2), and (c)(3) of this section.

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Dated: 11/5/98

November 5, 1998

Stephen F. Sundlof
Director, Center for Veterinary Medicine

[FR Doc. 98–???? Filed ??–??–98; 8:45 am]

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